UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,165	01/15/2004	Bruce Hammerberg	5051-661	4827

7590 06/14/2006

Kenneth D. Sibley
Myers Bigel Sibley & Sajovec, P.A.
P.O. Box 37428
Raleigh, NC 27627

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,165	HAMMERBERG, BRUCE	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 17-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-5,7-10,25 and 26* is/are allowed.

6)☒ Claim(s) *2, 6 and 21-24* is/are rejected.

7)☒ Claim(s) *17-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10, and 17-26 are pending.

2. In view of the amendment filed 4/4/06, all rejections are hereby withdrawn.

3. Claims 1, 3-5 and 25 and 26 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 7-10 and 17-24, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 10/11/05 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claims including all the limitations of an allowable product claim or rejoined process claim are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claims 1-10, and 17-26 are being acted upon in this Office Action.

5. Claims 17-20 are objected under 37 CFR 1.75 as being a substantial duplicate of claims 7-10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. Claim 21 is objected to under 37 CFR 1.821(d) because SEQ ID NO: is required for amino acid positions 356-374 of a mammalian IgE.

7. Claim 24 is objected to for minor informality: "antibodes" should have been "antibodies".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 21-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) an isolated monoclonal antibody that binds specifically to an epitope on canine IgE, cat and horse IgE as set forth in claims 1-6, (2) a method of testing for allergen reactivity of an IgE sample using the antibody as set forth in claims 7-20, and a test kit comprising the monoclonal antibody mentioned above for detection assay, **does not** reasonably provide enablement for (1) a method of detecting any mammalian IgE comprising providing any first antibody that specifically binds to any mammalian IgE at any epitope between amino acids "356-374" of any "mammalian IgE" as set forth in claims 21-24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only two monoclonal antibodies 5.91 and 3.76 (see page 9 of specification). The monoclonal antibody 5.91 binds specifically to an epitope on canine IgE wherein the epitope consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1. The same antibody also recognizes cat IgE epitope consisting of SEQ ID NO: 2 and horse IgE epitope consisting of SEQ ID NO: 3. The monoclonal antibody 3.76 binds to dog IgE epitope consisting of the amino acid sequence of SEQ ID NO: 9, cat IgE epitope consisting of the amino acid sequence of SEQ ID NO: 10 and horse IgE epitope consisting of the amino acid sequence of SEQ NO: 11. The antibodies are useful for detection assays.

The specification does not teach how to make any antibody that binds to all "mammalian IgE" at an epitope between amino acids 356-374 of any mammalian IgE as set forth in claims 21-

24. There is insufficient guidance as to the binding specificity of the claimed antibody because the epitope between amino acids 356-374 among "mammalian" IgEs such as IgE from dog, sheep, mouse, rat, pig and human differs. In fact, the specification at page 9 discloses that monoclonal antibody such as 3.76 that binds specifically to epitope consisting of the amino acids 146-162 of SEQ ID NO: 9 fails to bind to the same region in IgE from pig, sheep, mouse, rat or human. Likewise, the same reasons apply to monoclonal antibody that specifically binds to an epitope between amino acid positions 356-374 of all mammalian IgE (claim 21). Given that the amino acids residues between 356-374 of IgE from mammals such as human, pig, rat, dog, mouse, sheep, horse, cat, dog differ among the species of mammal, there is insufficient guidance as to the structure of the immunogen used to make antibody that specifically binds to all "mammalian IgE" at an epitope between said 356-374 amino acids of all mammalian IgE

Further, there is insufficient working example demonstrating that immunizing any peptide would produce antibody that binds to all mammalian IgE between amino acids 356-374 of any and all mammalian IgE.

Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide. Without the structure or amino acid sequence of the immunogen, it is unpredictable which antibody would bind specifically to an epitope between amino acids 145-166 or 356-374 of all mammalian IgE. Since the binding specificity of antibodies is not enabled, it follows that a test kit comprising the undisclosed antibodies and method of using said antibodies are not enabled.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

10. Claims 6 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) any first monoclonal antibody that binds to any epitope between amino acids 356-374 of any and all mammalian IgE in the claimed method, and (2) any antibody is coupled to any "binding pair" in claim 6.

The specification discloses only two monoclonal antibodies 5.91 and 3.76 (see page 9 of specification). The monoclonal antibody 5.91 binds specifically to an epitope on canine IgE wherein the epitope consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 1. The same antibody also recognizes cat IgE epitope consisting of SEQ ID NO: 2 and horse IgE epitope consisting of SEQ ID NO: 3. The monoclonal antibody 3.76 binds to dog IgE epitope consisting of the amino acid sequence of SEQ ID NO: 9, cat IgE epitope consisting of the amino acid sequence of SEQ ID NO: 10 and horse IgE epitope consisting of the amino acid sequence of SEQ NO: 11. The antibodies are useful for detection assays. The specification discloses only one biotin-avidin binding pair.

With the exception of the specific two antibodies mentioned above for detection assays, there is insufficient written description about the binding specificity of any other antibodies that bind to any epitope between amino acids 356-374 of all "mammalian IgE". Further, there is insufficient written description about the "epitope" between amino acids 356-374 of all "mammalian" IgE other than dog, cat and horse IgE to which the claimed antibody binds. This is because the epitope between amino acids 356-374 of dog IgE is different from the epitope between amino acids 356-374 of human IgE, or whale for example.

With regard to specific binding pair, the specification discloses only one specific biotin-avidin binding pair to which the antibody coupled. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of binding pair to describe the genus.

The specification discloses only two canine IgE antibodies that bind specifically to dog IgE at an epitope consisting of the amino acid sequence of SEQ ID NO: 1 or 9 that cross react with only cat IgE (SEQ ID NO: 2 or SEQ ID NO: 10) and horse IgE (SEQ ID NO: 3 or SEQ ID NO: 11), one of skill in the art would reasonably conclude that the disclosure fails to provide a

representative number of species of antibodies to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398; University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC2004).*

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 2 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "said dog IgE" in claim 2 has no antecedent basis in base claim 1. It is suggested that claim 2 be amended to recite "The antibody of claim 1, wherein said mammalian IgE is dog IgE and wherein said epitope is a dog IgE epitope SEQ ID NO: 9."

The "356-374 of mammalian IgE" in claim 21 is ambiguous and indefinite because it is not clear the amino acids residues 356-374 is from which mammalian IgE, the corresponding amino acid sequence (SEQ ID NO:) to which the claimed antibody binds. One of ordinary skilled in the art cannot appraise the metes and bound of the claimed invention.

13. Claims 1, 3-5, 7-10 and 25-26 are allowed.

14. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

16. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
June 9, 2006

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600